

REMARKS / ARGUMENTS

In response to the office action mailed July 12, 2007, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 11-17, 19, 21-28, 30-36, 38-39, and 41-48 under 35 U.S.C. §103(a).

On page 2, first paragraph, of the office action, the examiner has acknowledged Applicants' previous response filed April 3, 2007, and indicated that there have been no amendments to the claims. Applicants direct the Examiner to claim 19 which was amended previously to additionally recite "in an amount of about 1 kg or more."

Claims 11-17, 19, 21-28, 30-36, 38-39 and 41-48 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Rudat et al. (U.S. Patent No. 5,256,547) in view of Business Wire (Business Wire, "SangStat Announces Agreement with Eli Lilly for Manufacturing of CYCOPSPORINE; SangStat retains Worldwide Commercial Rights" Nov. 6, 1996, http://www.findarticles.com/p/articles/mimOEIN/is-1996Nov_6/ai_18835470.)

Rudat et al. has been cited for teaching a bulk quantity of cyclosporin A with an impurity level of less than 0.5% using HPLC. The Examiner readily admits that Rudat et al. teach a "bulk quantity" of only 61.5 g in Example 8. (Applicants submit that the previous amendment contained a typographical error on page 10, line 16, where "6.1 g of pure Cyclosporin A" should have read "61.5 g of pure Cyclosporin A.")

In contrast, Applicants' claims recite in relevant part: "a bulk quantity of cyclosporin in an amount of about 1 kg or more." A bulk quantity of about 1 kg or more is therefore not suggested in the teaching provided by Rudat et al.

Business Wire does not cure the deficiency of teaching provided by Rudat et al. Business Wire has been cited to show that bulk manufacturing of greater than 1 kg of cyclosporine was well known in the pharmaceutical industry. On page 4, first paragraph, of the office action, the Examiner has stated that "Business Wire published an article as far back as November 1996 (e.g., which would predate Applicant's 9/11/96 priority date) detailing years of previous development by SangStat for a proprietary cyclosporine to be

later produced in bulk, for which Eli Lilly was selected to do the bulk manufacturing.” (emphasis added).

In the first instance, Applicants’ priority date is September 11, 1996 based on GB 9618952. The publication date of Business Wire is November 6, 1996. Thus, the Business Wire printed publication does *not* predate Applicants priority date.

Further, the Business Wire publication does not evidence that at the time the invention was made, skilled artisans would have found bulk quantities of cyclosporin in an amount of about 1 kg or more obvious, since there is no evidence in Business Wire that any bulk quantities of about 1 kg or more could have been produced. The Examiner readily admits that SangStat previously developed cyclosporine “for a proprietary cyclosporine to be *later* produced in bulk, for which Eli Lilly was selected *to do* the bulk manufacturing.” See office action, page 4, first paragraph, and Business Wire, line 9: “Eli Lilly *will* fill and finish bulk CYCLOSPORINE.” See *also* page 2 of Business Wire:

This press release contains forward-looking statements that involve risks and uncertainties. The Company’s actual results may differ significantly from the results discussed in the forward-looking statements.

Factors that might cause such a difference include, but are not limited to, those risks associated the company’s ability to obtain regulatory approval for its CYCLOSPORINE, manufacturing of commercial quantities of CYCLOSPORINE on commercially favorable terms and the like.

Applicants respectfully submit that Rudat et al. only describe milligram and gram quantities of cyclosporin, not the presently claimed bulk quantities of about 1 kg or more. Business Wire does not provide *any* quantity of pure cyclosporin, much less an enabling disclosure of how to obtain bulk quantities of about 1 kg or more, - - only forward looking statements of an agreement to have Eli Lilly fill and finish bulk cyclosporine sometime after Nov. 6, 1996.

It was only after developing a counter current extraction process as disclosed in the present application, that cyclosporin in the bulk quantities and purity levels presently

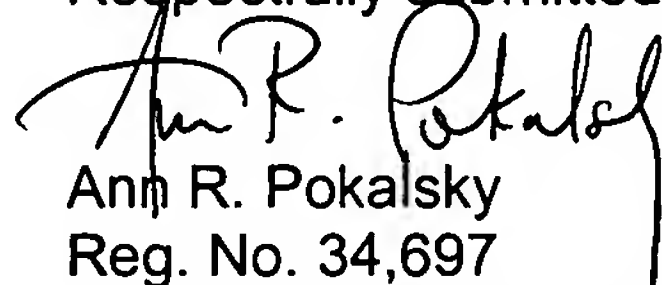
claimed, became obtainable. Thus, at the time the present invention was made, it was not, as the Examiner has posited on page 4 of the office action, merely a matter of judicious selection by the manufacturer to produce a bulk amount of 1 g, 500 g, 1 kg, or even "2 million kgs" of cyclosporin in the purity claimed, "depending on the number of e.g. prescriptions projected to be filled for the following month, year(s) as determined by the manufacturers client requests and internal marketing and research team."

Rather, as of the priority date of the present application, only by having the specification of the present application in hand would a skilled artisan have reasonably believed that pure, bulk quantities of cyclosporin as presently claimed were obtainable.

Since Rudat et al. in view of Business Wire fail to reasonably suggest the presently claimed product, claims 11-17, 19, 21-28, 30-36 38-39 and 41-48 are non-obvious and withdrawal of the rejection of these claims under 35 U.S.C. §103(a) is therefore warranted.

In view of the foregoing remarks, it is firmly believed that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,


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